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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,536	01/22/2002	Nobutaka Wakamiya	19036/36614A	7209

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,536

Applicant(s)

WAKAMIYA, NOBUTAKA

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 9-11 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7 and 9-11 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/600,950.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Application SN 10/054,536
Art Unit: 1645

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicant's preliminary amendments filed 01/22/02, 04/26/04 and 07/16/04. The amendment filed 04/26/04 is non-compliant and the one filed 07/16/04 is compliant.

Election

2) Acknowledgment is made of Applicant's election, with traverse, of invention III, claim 7, filed 04/26/04 in response to the restriction requirement mailed 03/25/04. Applicant's traversal is moot in light of Applicant's cancellation of claims 1-5 and 8.

Status of Claims

3) Claims 1, 3 and 5-11 were amended via the amendment filed 01/22/02.
New claims 12 and 13 were added via the amendment filed 01/22/02.
Claims 1-5, 8, 12 and 13 have been canceled via the amendment filed 7/16/04.
Claims 6, 7 and 9-11 have been amended via the amendment filed 7/16/04.
Claims 6, 7 and 9-11 are pending and are under examination. A First Action on the Merits on these claims is issued.

Sequence Listing

4) Acknowledgment is made of Applicant's submission of a paper and a computer readable copy of the Sequence Listing, which Listing has been entered.

Priority

5) The instant application is Divisional application of SN 09/600,950, now abandoned, which is a national stage 371 application of PCT/JP98/03311, filed 07/23/1998, which claims foreign priority to the application 10/11864, filed in Japan on 01/23/1998.

Information Disclosure Statement

6) Acknowledgment is made of Applicants' information disclosure statement filed 02/07/03. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Specification - Informalities

7) The instant specification is objected to for the following reason(s):

(a) The first paragraph of the instant application lacks information about the prior or application(s) as shown above under 'Priority'. Amendment to the specification is suggested.

(b) The use of trademarks in the instant specification has been noted in this application. For example, see page 43, last paragraph; "Superose 6"; page 44, line 14 and page 51, first paragraph; "Tween 20"; and page 50, last paragraph and page 44, middle paragraph: 'BlockAce'. The recitations should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix 1. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever such recitations appear.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 6, 7 and 9-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 6, 7 and 9-11 are indefinite and confusing in the recitation: 'Mannan-Binding Proteins', because it is unclear how an expression vector comprising cDNA corresponding to 66bp-812 of native MBP can express 'Mannan-Binding Proteins' as opposed to a Mannan-Binding Protein. For example in claim 7, is the expression vector expressing more than one Mannan-Binding Protein, each having a different molecular weight falling in the range of 1000-1300? Clarification is requested.

(b) Claim 6 is vague and indefinite in the limitation: 'inserting 66bp-812 of cDNA from native Human Mannan-Binding Proteins' because it is unclear how cDNA 'from

proteins' can be inserted, since cDNA does not originate from a protein. What does the limitation 'from' encompass in terms of scope is not clear.

(c) Claim 6 parts (b) and (c) are confusing in the recitation: 'preparing transformants by introducing vector into CHO cells'. It is unclear what are encompassed in the term 'transformants'. Are these transformant cells?

(d) In order to avoid redundancy and for clarity, in dependent claims 7, 9 and 10, it is suggested that Applicant replace the limitation 'Recombinant Human Mannan-Binding Proteins (rhMBP)' with --rhMBP--.

(e) Claim 11 is confusing and/or incorrect in the limitation: 'Proteins which is' [Emphasis added].

(f) Claims 7 and 9-11, which depend from claim 6, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11) Claim 11 is rejected under 35 U.S.C § 102(a) as being anticipated by Ma *et al.* (*J. Biochem.* 122: 810-818, October 1997).

The transitional term 'comprising' in the instant claims is interpreted as being equivalent to 'having'.

Ma *et al.* taught recombinant human mannan-binding proteins, i.e., rhMBP, having molecular weights in the range of 200-1,300 kDa (which is encompassed in the recited range of 1000-1300 kDa) by gel filtration chromatography (see abstract; page 812, left column, first paragraph; and Figure 6A). The recombinant human mannan-binding proteins having a molecular weight of 1150 kDa are taught by Ma *et al.* (see Figure 6A).

The instant claim is a product-by-process claim, which is not limited to the manipulations of the recited steps, but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicant has not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicant has not shown that the underlying structure of the prior art rhMBP differs from that of the instantly claimed rhMBP.

Claim 11 is anticipated by Ma *et al.*

12) Claims 6, 7, 9 and 11 are rejected under 35 U.S.C § 102(a) as being anticipated by Otani *et al.* (*Nippon Men'eki Gakkai Soaki, Gakujutsu Shukai Kiroku* 27: 182, 29 September 1997 – Original and English translation) as evidenced by Stanislawski *et al.* (US 2004/0170653).

Otani *et al.* taught a method of constructing the expression system of human MBP in eukaryotic cells by using the same art-known pNOW1 expression vector that is used for the expression of bovine conglutinin and expressing the recombinant human MBP. The method comprises introducing the cDNA of the human MBP (i.e., inclusive of 66-812 bp) into the pNOW1 vector and constructing the plasmid pNOW-hMBP. The vector is then introduced to dhfr- CHO cells. Then the G418-resistant (i.e., neomycin resistant) stock clones are obtained. The stock clones are then cultured in the presence of MTX, and the MTX resistant cells are selected. The hMBP expressed in high amounts is obtained, which inhibits the erythrocyte agglutination (i.e., haemagglutination) caused by influenza virus (see entire English translated publication). The molecular weights recited in claims 7 and 8 are viewed as properties inherent to Otani's human MBP. That the prior art G418-resistant cells represent neomycin-resistant cells is also inherent from the teachings of Otani *et al.* in light of what is known in the art. For instance, see the Table under section [0028] of Stanislawski *et al.*

Claims 6, 7, 9 and 11 are anticipated by Otani *et al.*

Objection(s)

- 13)** Instant claims are objected to for the following reason(s):
- (a) Claims 7 and 9 are objected to for not leaving a space in between '280nm'.
 - (b) In the last line of claims 7 and 9, for clarity, it is suggested that Applicant replace the recitation "Gel-Filtration Chromatography" with --gel filtration chromatography--.

Remarks

- 14)** Claims 6, 7 and 9-11 stand rejected.
- 15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.
- 16)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 17)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004